TMDA
Tanzania Medicines & Medical Devices Authority

DRUG SAFETY Bulletin

Vol. 5 - 2025

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VISION

To be the leading regulatory authority in ensuring safe, quality, and effective medicines, medical devices, diagnostics, and other health-related products for all.

MISSION

To protect and promote public health by ensuring the quality, safety, and effectiveness of medicines, medical devices, diagnostics, and other health-related products.

PHILOSOPHY

TMDA strives to offer quality regulatory services in the pursuit of protecting public health and the environment by using competent and dedicated staff.

Editorial Note

Dear readers,

It is with great pride and commitment that we present to you the 5th Edition of the Drug Safety Bulletin – 2025, a continued effort by the TMDA to enhance the transparency, awareness, and dissemination of vital regulatory information regarding the quality, safety, and effectiveness of medicines, medical devices, and diagnostics in Tanzania.

As mandated by the Tanzania Medicines and Medical Devices Act, Cap. 219, TMDA is entrusted with the responsibility to ensure that all medical products available to the public meet the highest standards of safety, efficacy, and quality.

Maintaining Maturity Level 3 under the WHO Global Benchmarking Tool (GBT) is a strong affirmation of our commitment to regulatory excellence, and further emphasizes the importance of keeping stakeholders well-informed.

The Drug Safety Bulletin continues to serve as a key platform for sharing updates on pharmacovigilance, regulatory actions, safety alerts, and other relevant drug safety information. Through this publication, we aim to engage healthcare professionals, industry stakeholders, and the general public in a collaborative effort to promote the rational and safe use of medicines and medical devices.

In this edition, we present a collection of important safety updates, quality monitoring reports, and case studies that reflect the evolving landscape of medicines regulation and highlight our continued vigilance in protecting public health.

I invite all readers to explore the contents of this bulletin, and I warmly welcome your feedback and suggestions to improve the content, design, and relevance of future issues.

Your engagement is invaluable in our collective journey toward strengthening pharmacovigilance and regulatory systems in Tanzania.

With thanks for your continued vigilance,

Dr. Adam Fimbo
Editor-in-Chief

Acknowledgements

On behalf of the TMDA, it is my sincere pleasure to express profound gratitude to all who contributed to the development and successful publication of this drug safety bulletin.

I am particularly indebted to the dedicated staff of the Clinical Trials Control and Pharmacovigilance Section, whose tireless efforts and expert crafting were instrumental in bringing this vital document to fruition.

Equally essential is the commitment shown by the focal persons of Pharmacovigilance (PV) Centres countrywide. Your vigilance and successful, timely communication of Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs) are the foundation of our safety monitoring.

Furthermore, we acknowledge the Medical Officers in Charge for their crucial leadership in supervising and providing the necessary support to these focal persons.

The World Health Organization (WHO) and the Gates Foundation (GF) are also acknowledged for their support in strengthening the systems and tools used in collecting, reporting and analysis of data submitted.

Dr. Yonah H. Mwalwisi
Director of Human and Veterinary Medicines

Updates on spontaneous reporting of medicines safety

To ensure protection of patients and the general public from risks associated with the use of medicines, TMDA collects reports of adverse events following drug administration and immunization occurring to consumers. These reports are analyzed and assessed to establish the benefit and risk profile of medicines and help the Authority in making informed regulatory decisions. The spontaneous system, which involves unsolicited reporting of suspected adverse drug events by healthcare workers and the community, has been the mainstream in the country since 1989. These reports, along with data from active surveillance clinical trials and epidemiological studies, provide a comprehensive understanding of the safety profile of the medicinal product.

TMDA has continuously enhanced spontaneous reporting of adverse events by establishing several reporting tools. The traditional paper-based reporting tools (yellow and green forms) used by healthcare workers (HCWs) and patients, respectively, have been supplemented by electronic tools such as Safety and Quality Reporting Tool (SQRT) App, and SQRT Web to cope with the over changing global technology. The SQRT App is available in the Google Play Store, the SQRT Web is accessible through the TMDA Website or via the link sqrt.tmda.go.tz.

In addition, the use of unstructured supplementary service data (USSD) code *152*00# and Toll-free number (0800 1100 84) by the community for notification of adverse events experienced has been promoted by the Authority. Nevertheless, the Authority has domesticated the WHO electronic tool (VIGIMOBILE App) for reporting of Adverse Events Following Immunization (AEFIs).

As a result of these innovations, the reporting of Adverse events by healthcare workers and the general public has increased over time. In fact, TMDA has managed to reach the WHO target of 200 Adverse drug reactions reports per 1,000,000 population (Tanzania population = 59,851,347, (the last official Population and Housing Census, 2022)) in the last two (2) financial years 2023/24 and 2024/25 **(Figure 1).**

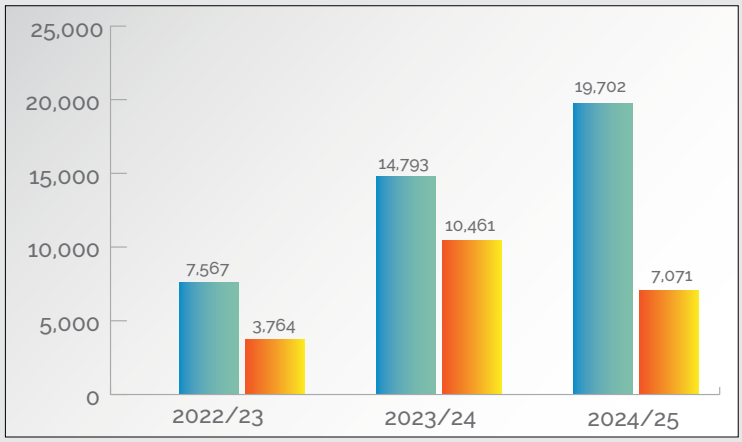

Figure 1: The number of ADR and AEFI reported for the financial Year 2022/23, 2023/24 and 2024/25

Impact of the Deployment of Vigimobile on AEFI reporting

In June 2023, TMDA, in collaboration with the WHO, Immunization and Vaccines Development (IVD) program and the President's Office - Regional Administration and Local Government (PORALG), successfully launched the VigiMobile - electronic reporting system. This initiative aimed to enhance the reporting of Adverse Events Following Immunization (AEFI) in Tanzania.

Training on the use of VIGIMOBILE to healthcare workers, council health management teams (CHMT) and regional health management teams (RHMT) has been done in 17 out of 26 regions in Tanzania Mainland. The regions covered are: Phase I - Dar es Salaam, Dodoma, Pwani, Tanga, Kilimanjaro, Manyara, and Arusha; Phase II - Kigoma, Katavi, Songwe, Rukwa, Mbeya, and Kagera; Phase III - Mtwara, Iringa, Lindi, and Singida. A total of 46 TOT at the national level, 520 CHMT and RHMT team members and 4842 vaccinators were trained.

VigiMobile Application has facilitated efficient and real-time reporting and data quality, and has significantly increased the number of AEFI reports received by the Authority. A total of 16,947 AEFI reports have been reported through VIGIMOBILE App compared to 2,560 reports that were received through paper-based reporting since its inception to 30 June 2025.

Photo 1: Director of Human and Veterinary Medicines (Third from the left – sitting) in a group photo with participants during inauguration of Training on VIGIBOBILE Application to National Facilitators conducted in Dar es salaam on **May, 2023**

Updates on investigation and causality assessment of serious Adverse Drug Reactions and Serious Adverse events following immunization

TMDA, in collaboration with the President's Office, Regional Administration and Local Government (PORALG) and the Ministry of Health, has accomplished appointment and training of investigation teams in 184 councils and 36 National, Zonal and Regional Referral Hospitals in the country. All the teams have been trained and provided with Terms of Reference and tools to enable the investigation of adverse events.

Due to these collaborative efforts, the number of serious adverse drug reactions (ADRs) and Adverse Events Following Immunization (AEFIs) being investigated and assessed for causal association has increased over time **(Figure 2)**.

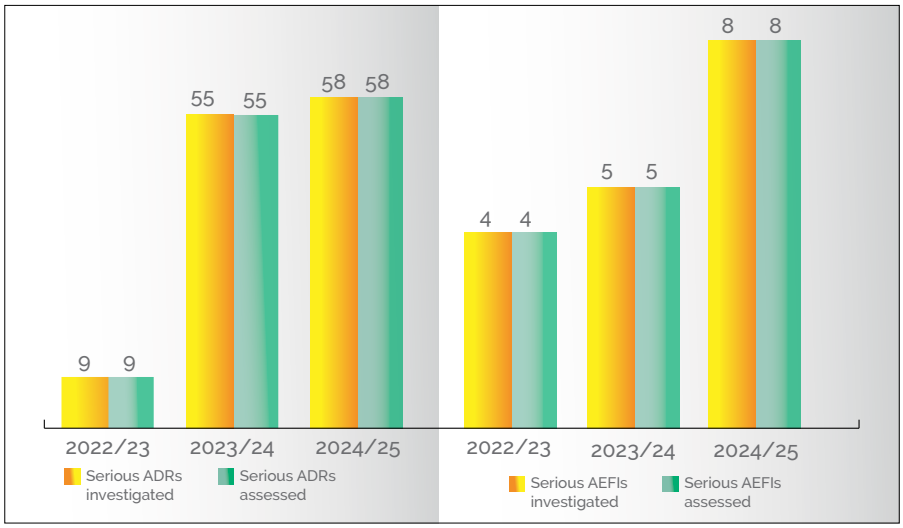

Figure 2: The number of serious ADRs and AEFIs investigated and assessed for the financial Year 2022/23, 2023/24 and 2024/25.

Figure 3: Training of the ADRs and AEFI investigation team at Benjamini Mkapa Zonal Referral Hospital in October, 2024 (left) and Chato Zonal Referral Hospital in July, 2024 (right)

Training, Sensitization and Supportive Supervision

10,736

healthcare workers were trained from July, 2022

TMDA has consistently implemented a range of strategies to strengthen the reporting of adverse drug reactions (ADRs) and adverse events following immunization (AEFIs) by healthcare workers and the community nationwide. These strategies include training, sensitization, and supportive supervision of healthcare professionals on pharmacovigilance.

Between July 2022 and June 2025, a total of 2,936 health facilities were reached, and 10,736 healthcarwwe workers were trained in pharmacovigilance **(Figure 4)**.

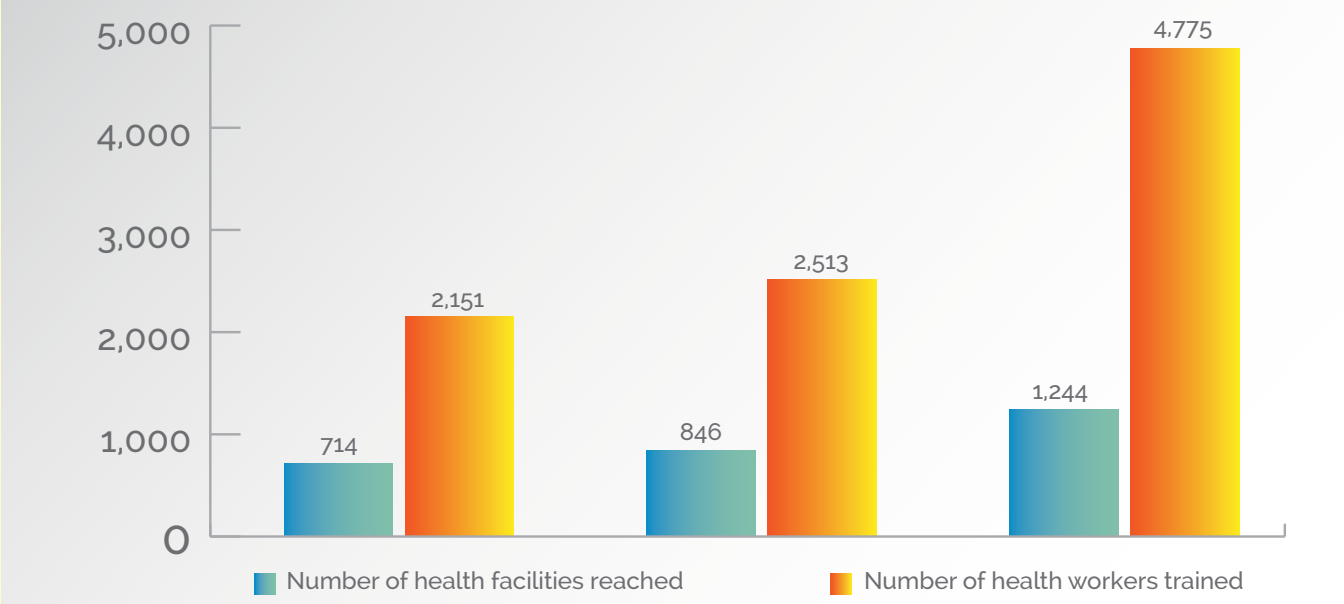

Figure 4: The number of facilities reached during the supervision of PV centres in the financial year 2022/23, 2023/24 and 2024/25

During the same period, TMDA conducted pharmacovigilance supportive supervision visits to 285 health facilities across 19 of the 26 regions in mainland Tanzania. These efforts aimed to enhance the detection, management, and reporting of adverse drug reactions and adverse events following immunization. The regions covered included Dar es Salaam, Arusha, Morogoro, Iringa, Mara, Simiyu, Kilimanjaro, Singida, Njombe, Mbeya, Dodoma, Manyara, Tabora, Lindi, Geita, Kibaha, Mtwara, Mwanza, and Tanga. In each region, 15 health facilities were visited.

A group photograph of Saohill and Lepurko Ward leaders, Ward Executive Officers, Head Teachers of Schools, Local Government Chairpersons, and TMDA Officials taken during the Pharmacovigilance Community Engagement Session held in Mafinga Town Council, Iringa Region in October, 2024

Group photo of participants from 13 district hospitals across the country during the Pharmacovigilance Task Force training, held at Magadu Conference Centre in Morogoro Municipality in September, 2024

Ms. Hawa Saburah, Drug Inspector at TMDA, delivered a presentation during the Pharmacovigilance Training session held at the TMDA Eastern Lake Zone office in Mwanza in May, 2025

300,740
IEC materials were distributed

Additionally, as part of community sensitization on reporting Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs), a total of 300,740 Information, Education, and Communication (IEC) materials including brochures, infographics, flyers, and posters were distributed across 26 regions of Tanzania between July, 2022 and June, 2025.

Group photograph of TMDA staff taken during the training session on the SQRT electronic reporting tool and awareness sensitization on adverse drug reaction (ADR) reporting, held at the TMDA Eastern Zone Office, Dar es salaam in March, 2025

Distribution of pharmacovigilance IEC materials and sensitization on adverse drug reaction (ADR) reporting conducted for healthcare professionals at Njombe Town Council Hospital in February, 2023

Ms. Seraphina Cleophace, pharmacovigilance focal person TMDA Central Zone, presents pharmacovigilance IEC materials to the Hospital Director of Mbeya Zonal Referral Hospital in January, 2023

Increase in the number of Pharmacovigilance centres

From July 2022 to June 2025, the number of pharmacovigilance centres in Tanzania increased significantly from 7 to 36, comprising 1 national, 5 zonal, 26 regional, and 4 specialized hospital centres. This expansion aims to establish a robust and stringent pharmacovigilance system to enhance the reporting of adverse events across the country.

Furthermore, TMDA has developed comprehensive Guidelines for the Operationalization of Pharmacovigilance Centres. Training sessions have been conducted to focal persons and supporting staff at these centres, equipping them with the necessary operational tools. Each pharmacovigilance centre has formally appointed a focal person responsible for overseeing and coordinating all pharmacovigilance activities.

Post-marketing surveillance of medicines

Post-market surveillance (PMS) refers to the continuous monitoring of the quality, safety and efficacy of medicines available on the market after their registration. This process involves the collection of medicine samples, verification of product information accuracy, and laboratory analysis to ensure product quality.

Since 2007, TMDA has been implementing PMS through various programs targeting multiple categories of medicines, including antimalarials, antiretrovirals, anti-tuberculosis drugs, antibiotics, analgesics, and veterinary medicines. The PMS program typically encompasses medicine sampling from the market, laboratory testing, and dissemination of the results.

Between 2020 and 2024, TMDA successfully conducted three structured PMS programs, as detailed in the table below:

Table 1: PMS programs and types of medicines selected for monitoring from 2020-2027

Year	Human Medicinal Products	Veterinary Medicinal Products
2020	▪ Anti-malarial ▪ Anti-retroviral ▪ Anti-TB	-
2020-2023	▪ Antihypertensive ▪ Antidiabetics ▪ Antibiotics ▪ Antiprotozoal ▪ Antimalaria ▪ Anthelmintics	▪ Antibiotics ▪ Anthelmintics
2023	▪ Anti-malarial ▪ Anti-retroviral ▪ Anti-TB ▪ Covid-19 vaccines	-
2024-2027	▪ Antihypertensive ▪ Antidiabetics ▪ Antibiotics ▪ Antiprotozoal ▪ Antimalaria ▪ Blood thinner (Aspirin Junior) ▪ Uterine inducer (Oxytocin in) ▪ IV fluids (RL)	▪ Antibiotics ▪ Anthelmintics ▪ Vaccines (CBPP and Tatu moja).

Pharmacovigilance Projects in Tanzania Mainland

TMDA has regularly conducted a number of projects to strengthen pharmacovigilance activities in the country. Some have been completed and others are ongoing: -

Completed Projects

a. Two (2) European and Developing Countries Clinical trials Partnership (EDCTP) funded projects; PhArmacoVIgilance Africa (PAVIA) from 2018 to 2022, and Pharmacovigilance infrastructure and post-marketing surveillance system capacity building (PROFORMA) from 2018 to 2024;

b. Management Sciences for Health - The Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program from 2021 to 2023

Ongoing Projects

a. Saving Lives and Livelihood (SLL) from 2022, funded Africa CDC and the Mastercard Foundation; and

b. African Union Smart Safety Surveillance (AU-3S) Project from 2024 under African Union Development Agency (AUDA) – New Partnership for Africa Development (NEPAD) funded by the Gates Foundation (GF).

These projects contributed significant strides in strengthening pharmacovigilance activities as follows:-

a. TMDA attained and maintained a WHO maturity Level 3;

b. Increased number of adverse drug reactions and adverse events following immunization to reach the WHO targets;

c. Improved Pharmacovigilance activities in public health programme through development of pharmacovigilance tools and shared activities such as active surveillance and capacity building programs;

d. Strengthened the capacity of TMDA staff and healthcare Workers in pharmacovigilance activities through long-term and short-term training;

e. Enhanced public trust in medicines and the healthcare system through continued medicines safety surveillance, data collection and regulatory decisions to ensure public protection;

f. Increased number of Pharmacovigilance experts in the country due to the establishment of a training curriculum for undergraduates and postgraduates' degrees in pharmacovigilance and pharmacoepidemiology;

g. Streamlined reporting of adverse by establishment, strengthening and upgrading of electronic reporting tools;

h. Strengthened pharmacovigilance centres through capacity building and infrastructure development (e.g. supply of computers); and

i. Reinforced Pharmacovigilance Oversight to Marketing Authorization Holders through Good Vigilance Practices (GVP) Inspection and training of qualified personnel for pharmacovigilance

Regulatory actions due to safety and quality issues

The Authority institutes all necessary legal actions to protect the public. The enforcement includes but is not limited to withdrawal of products, recall of batches, de-registration of products, prosecution of offenders, institution of disciplinary proceedings as per the Law, and any other necessary legal action(s). TMDA has taken the following regulations due to safety and quality issues.

1 Revocation of Marketing Authorization for Medicinal Products Containing Ampicillin Active Ingredient as Monotherapy

The marketing authorization of all medicinal products containing ampicillin as a monotherapy (a single ingredient) across all dosage forms was cancelled **(Public Notice 3rd June, 2024) Annexe 1)**.

The cancellation was unavoidable following a comprehensive public health review assessing the quality, safety, and efficacy of medicinal products containing ampicillin. The review concluded that several microorganisms—including *Klebsiella pneumoniae, Escherichia coli,* other *Klebsiella* species, and Proteus species—have developed significant resistance to ampicillin monotherapy. Some studies reported resistance levels reaching up to 100% in certain East African Partner States.

This resistance is primarily due to these bacteria producing enzymes known as -lactamases (or penicillinases), which break the -lactam ring—an essential component of the ampicillin molecule required for the drug to attack the bacterial cell wall. Once the ring is cleaved, ampicillin is rapidly inactivated and rendered ineffective.

This decision is a vital public health measure aimed at combating antimicrobial resistance (AMR) and ensuring that medicinal products remain effective. Marketing Authorization Holders (MAHs) have been advised to reformulate their products by combining ampicillin with -lactamase inhibitors, such as sulbactam. These inhibitors protect ampicillin from enzymatic destruction, allowing it to remain active and effectively eliminate the bacteria.

2 Guidance on Intrathecal Injection of Medications

Intrathecal Bupivacaine Injection is an amide long-acting local anaesthetic commonly used to provide pain relief during surgical, obstetric, and dental procedures as well as postoperative pain management.

Between January 2021 and June 2022, nine (9) reports of serious Adverse Events (ADRs) associated with the use of Bupivacaine injection were received. The ADRs were hypotension, nausea, vomiting, headache, bradycardia, and rare cases of convulsions, neurotoxicity, allergic reactions, and cardiotoxicity. The investigation of these events revealed that: -

a. Heavy Bupivacaine was more associated with the reported adverse drug reactions as compared to light Bupivacaine;

b. All facilities did not have intralipid emulsion, an essential medicine used for reversing both neurologic and cardiac toxicity complications from spinal anaesthesia;

c. Deaths associated with Bupivacaine injections were reported from most of the facilities with neither anesthesiologists nor active Medicines nor Therapeutics Committees (MTCs) on monitoring of safety of medicines;

d. All five samples of suspected Bupivacaine injection collected and tested at the TMDA laboratory complied with the quality control parameters; and

e. All nine (9) reported fatal events were due to known (systemic) Bupivacaine adverse drug reactions and were related to administration practice.

As part of Correction and Preventive Actions (CAPA), the Ministry of Health, in collaboration with the Society of Anesthesiologists of Tanzania (SATA), issued a Practice Guideline for Prevention of Incorrect Intrathecal Injection of Medications **(Annexe 2)**.

3 Recall of substandard and falsified products

In the 2023/2024 period, the TMDA identified a total of eleven (11) substandard human medicines circulating on the Tanzania market, as provided in Table 1. Additionally, one falsified veterinary product—Levafas Diamond Fluke and Worm Drench 500 ml (TAN 00, 038 PO2X NOR)—was detected. The falsified product, falsely claimed to be manufactured by Norbrook Kenya Limited, exhibited discrepancies in labeling, bottle color, presence of the SN1 and HDPE logo, and batch number.

To safeguard public and animal health, TMDA issued a public notice and implemented a coordinated nationwide recall and safe disposal of the identified products across all TMDA zones.

Table 1: A list of substandard medicines identified and recalled from the Tanzania market in the year 2024

S/N	Name, Batch No., Manufacturing and Expiring Dates	Description of the Issue
1.	Mesporin powder for infusion (Mesporin 500mg, Batch No. Z0030Z0129) and Mesporin 2000mg IV, batch No. Z0057 and Z0107) manufactured by Labesfal Almiro Laboratories S.A., Zona Industrial do Lagedo, 3465-157 Santiago de Besteiros, Portugal.	The product was observed with visible particles (polystyrene) in the reconstituted powder of the product.
2.	Emina Povidone Iodine 10% Batch no. A00073-1 was manufactured by Bingwa Laboratories Limited. Manufactured: November 2022 and expiring: November 2025.	The product was observed to be soapy instead of the deep, dark brown solution.
3.	Ringer Lactate Infusion (Compound Sodium Lactate Intravenous Infusion BP) batch No. 040070823 manufactured by Kairuki Pharmaceuticals Industry Limited (KPIL), Kibaha, Pwani. Manufactured: July 2023, Expiring: July 2025	The product was observed with mould-like growth and inconsistency in manufacturing and expiry date. The same batch has two different men. & exp. Dates.
4.	Badex 0.2% (Dexamethasone Injection 50mL, Reg. No. TZ 15 V 0014) with importation permit No. TMDA-WEB0323/D/IPER/0129. Manufactured by Hebei Yuanzheng Pharmaceutical Co., Ltd, China	Brand name printed as "Badex" instead of "Badex 0.2%".
5.	XSONE N (Dexamethasone Sodium Phosphate 0.1% W/V & Neomycin Sulphate 0.35%W/V 5ML) Sterile Eye/Ear Drops, Batch No. 69E00123 (Manufactured: May 2023 & Expiring: October 2025) and batch No. 69D02323 (Man. Apr. 2023 & Exp. Sept. 2025)	Presence of brown sediments at the bottom of the bottle (vials)
6.	Mucogel (Aluminium Hydroxide + Magnesium Hydroxide + Oxethazaine Gel) 125 mL, Batch No. 2201197 and 2201198; Manufactured: February 2022 by Egyptian Int Pharmaceutical Industries Co., Egypt and expiring: February 2025.	The complained batches were reported to have changed physical characteristics by forming dense/thick sediment (caking) that settles at the bottom of the bottle even after vigorous shaking of the bottle.
7.	Hydopa (Methyldopa 250 mg), Batch No. 84426 (Manufactured: September 2023 and Expiring: August 2026), Batches No. 83737 and 83738 (Manufactured: June 2023 and Expiring: May 2026), manufactured by Laboratory & Allied Limited, Nairobi, Kenya and distributed by Medical Stores Department (MSD).	The complained batches were observed to have changed their physical appearance from their original yellowish colour to brownish yellow, with cracks observed on their physical appearance.
8.	Glimet 1 (glimepiride and Metformin Hydrochloride Tablets (1mg & 500mg) manufactured by Acme Formulation Pvt. Ltd., India	Reported to have poor efficacy. Did not provide expected results.
9.	Glimet 2 (glimepiride and Metformin Hydrochloride Tablets (2mg & 500mg) manufactured by Acme Formulation Pvt. Ltd., India	Reported to have poor efficacy. Did not provide expected results.
10.	Phenoxymethyl Penicillin 250mg tablets (DIOPEN) BN: 060011122, 060031122 & 060041122. Man Date: November 2022. Exp Date: October 2024 by Keko Pharmaceutical Industries (1997) Ltd	The reported batches were observed to have Chipping, Lamination, and discolouration (yellow-colored spots)

Annexe 1

ISO 9001: 015: CERTIFIED

PUBLIC NOTICE

3rd June, 2024

NOTICE OF REVOCATION OF MARKETING AUTHORIZATION FOR MEDICINAL PRODUCTS CONTAINING AMPICILLIN ACTIVE INGREDIENTS AS MONOTHERAPY

1. Tanzania Medicines and Medical Devices Authority (TMDA) is mandated as per section 5(1) of the Tanzania Medicines and Medical Devices Act Cap, 219 to protect public health by ensuring medicinal products' quality, safety and efficacy.
2. TMDA has recently conducted a thorough and comprehensive assessment of all products containing ampicillin as a single moiety. Following this review, it has been clear that microorganisms including Klebsiella pneumoniae, Escherichia coli, other Klebsiella spp, and Proteus spp have demonstrated resistance towards ampicillin monotherapies. Some of the reviewed articles during this assessment have also indicated that resistance has reached up to 100% in some East African Partner States.
3. In view of this and pursuant to section 51 (1) (a) and (b) of the Tanzania Medicines and Medical Devices Act Cap, 219, the Authority has decided to cancel the marketing authorization of medicinal products containing ampicillin as monotherapy across all dosage forms.
4. All marketing authorization holders of the affected products are advised to reformulate their products to different combination to allow for the same to be effective against bacterial infections.
5. Similarly, the Authority would like to inform its esteemed stakeholders that, the new applications for registration or renewal applications of ampicillin monotherapy products will not be accepted.

Issued by:
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Annexe 2

Practice Guideline for Prevention of Incorrect Intrathecal Injection of Medications The Ministry of Health and The Society of Anaesthesiologists of Tanzania (SATA) strongly urge all anaesthesia providers to abide to standard guidelines of anaesthesia practice. The implementation of the following "modified Tighe simple 10-step systems solution" for minimizing the chance of inadvertent intrathecal administration of wrong drugs during spinal anaesthesia is STRONGLY recommended.

1. Reaffirm the **consent for the procedure** and **position the patient properly** for spinal /epidural anaesthesia administration
2. Identify the **correct site** for needle introduction; **inject local anaesthetic (e.g. Lignocaine)** into the skin for analgesia and discard the solution.
3. Ask the **Anaesthetic Assistant** to **apply the first skin antisepsis solution** while the **Anaesthetist scrubs and aseptically gowns** (ensure sterile gown, gloves, hat and mask).
4. Open a separate spinal administration pack/set, the **gowned anaesthetist apply secondary skin antisepsis**, allow to dry
5. Apply the prepacked **sterile drapes to ensure adequate sterile field for the procedure**
6. Take a single syringe and discard any others that might be in the pack if prepacked;
7. **Double checking Mechanism**-Check the proposed drug(s) to be injected with the anaesthetic assistant, by each reading out loud what is written on the ampoule(s), independently of, but immediately after, each other.
8. **Draw up the exact calculated drug dose (e.g.Bupivacaine) for intrathecal injection**, keep the syringe in the pack and discard all unused drugs;(single use vials/ampoules)
9. **Perform intrathecal injection** as per recommended standards and ensure free clear Cerebral Spinal Fluid (CSF) flow
10. **Inject the calculated dose** of the anaesthetic solution in the only syringe available in the spinal pack or procedure tray, dress site and position the patient.

Publications

Between May, 2022 to July, 2025, TMDA successfully published six (6) manuscripts in peer-reviewed Journals as described hereunder;

First publication;

Title:

Incidence and determinants of adverse events in individuals with HIV commencing Dolutegravir-based antiretroviral therapy in mainland Tanzania.

Available at: https://pubmed.ncbi.nlm.nih.gov/38182720/ OR DOI: 10.1038/s41598-023-51144-7"

This was a cohort event monitoring study to determine the profile, nature and determinant of occurrence of adverse events. It was noted that the most frequently experienced AE was skin itching and rashes (15/62; 24.2%). DTG-associated neuropsychiatric AEs were less common and included headache (6 [9.6%]) and sleep disturbances (3 [4.8%]). The overall incidence of occurrence of the first AEs was 96.7 per 1000 person-months [95% C.I: 74.4-125.7], with the highest incidence observed among the elderly (≥ 60 years). Individuals on WHO HIV Clinical Stage 2 had a 2.7 significantly higher risk of developing AEs (adjusted hazard ratio = 2.73, 95% CI = 1.46-5.12, p = 0.017). A low incidence of grade I (mild) and grade II (moderate) DTG-associated AEs suggests that the regimen is generally safe in the population. Continued monitoring of DTG safety in the population is recommended

Second Publication;

Title:

Lessons from enriching Tanzania's clinical research ethics clinical trials oversight and pharmacovigilance through the ASCEND project

Available at: https://link.springer.com/article/10.1186/s12982-024-00180-3

Third Publication:

Title:

A Comprehensive Assessment of Quality of Antimalarial Medicines in Mainland Tanzania: Insights from Five Years of Postmarket Surveillance

Available at: https://www.ajtmh.org/view/journals/tpmd/111/6/article-p1215.xml OR DOI: https://doi.org/10.4269/

Sustainable access to high-quality antimalarial medicines is pivotal to achieving universal and effective malaria control. Poor-quality antimalarial medicines are prevalent in sub-Saharan Africa, impeding malaria control initiatives and claiming the lives of many children. Regular monitoring of the quality of antimalarial medicines is crucial to ensure the quality of service to the community. A cross-sectional study using a postmarket surveillance (PMS) approach was conducted from 2019 to 2023. Antimalarial samples (n = 2,032) were collected from the port of entry, local manufacturers, and various distribution outlets in 15 regions of mainland Tanzania. The samples were subjected to tier 1 evaluation, comprising a product information review (PIR) and identification using the Global Pharma Health Fund-MinilabVR techniques. Samples that failed the identification tests and 10% of the samples from distribution outlets that passed the tests were subjected to confirmatory testing (tier 2),

which included assays, related substances, dissolution, and sterility per the pharmacopeial monographs. During five annual PMSs, 2,032 antimalarial samples were collected and subjected to quality tests. All samples complied with the standard specifications for identity, dissolution, related substances, sterility, physical evaluation, disintegration, and assay. A total of 292 (55.5%) tested samples failed the PIR evaluation, with incomplete package information in leaflets contributing to 64.7% of all deviations. Antimalarial medicines circulating in the mainland Tanzanian market meet expected quality standards. Continuous monitoring of the quality of antimalarial medicines is recommended.

Fourth Publication

Title:

Post marketing surveillance of selected veterinary medicines in Tanzania mainland

Available at: https://pubmed.ncbi.nlm.nih.gov/35681204/ OR doi: 10.1186/s12917-022-03329-x.

Veterinary medicines have been widely used for the prevention and treatment of animal diseases. Globally, the veterinary medicine industry is growing. However, there is a significant increase of concern on the quality of veterinary medicines in various developing countries' legal markets. Poor-quality medicines are associated with treatment failure, development of drug resistance, increased healthcare cost, and death. These reasons warrant a need for monitoring the quality of the medicines circulating in the Tanzania Mainland.

This was a survey study and veterinary medicines samples were collected from 9 out of 26 regions of Tanzania mainland between 2014 and 2017. Veterinary medicines were sampled from wholesale pharmacies, retail pharmacies, veterinary clinics and Veterinary Accredited Drug Dispensing Outlets (ADDO-vet). All sampled medicines were subjected to product information review and full quality control testing at the Tanzania Medicines and Medical Devices Authority-World Health Organization prequalified laboratory.

A total of 238 samples of veterinary medicines were collected. Out of these, 97.1% (231/238) were subjected to full quality control testing and product information review. All sampled veterinary medicines conformed to visual appearance, clarity, pH, solubility and sterility tests. Also, of the sampled veterinary medicines 97.8% (226/231) and 89.2% (206/231) passed identification and assay tests, respectively. As well as, the majority of the collected samples 92% (219/238) failed to comply with product information requirements. The most observed deficiencies on product information were inadequate information on the package insert 94.1% (224/238), inappropriate storage conditions 55.5% (132/238) and lack of Tanzania registration number 27% (64/238).

Veterinary medicines with poor quality were found circulating in the legal markets of Tanzania. This can potentiate treatment failure and the development of drug resistance in animals and humans. Post marketing surveillance program will continue to be implemented to ensure that only good quality, safe and efficacious medicines are circulating in the Tanzania Mainland market.

Fifth Publication

Title:

Safety and Tolerability of Ivermectin and Albendazole Mass Drug Administration in Lymphatic Filariasis Endemic Communities of Tanzania: A Cohort Event Monitoring Study.

Available at: https://pubmed.ncbi.nlm.nih.gov/35631420/ OR doi: 10.3390/ph15050594.

Ivermectin and albendazole (IA) combination preventive chemotherapy to all at-risk populations is deployed to eliminate lymphatic filariasis. Although safety monitoring is imperative, data from Sub-Saharan Africa is scarce. We conducted a large-scale active safety surveillance of adverse events (AEs) following IA mass drug administration (MDA) to identify the type, incidence, and associated risk factors in Tanzania. After recording sociodemographic, clinical, and medical histories, 9640 eligible residents received single-dose IA combination preventive chemotherapy. Treatment-associated AEs were actively monitored through house-to-house visits on day 1, day 2, and day 7 of MDA. Events reported before and after MDA were cross-checked and verified to identify MDA-associated AEs. 9288 participants (96.3%) completed the seven-day safety follow-up, of whom 442 reported 719 MDA-associated AEs. The incidence of experiencing one or more type of MDA-associated AE was 4.8% (95% CI = 4.3–5.2%); this being significantly higher among those with Pre-MDA clinical events than those without (8.5% versus 4.1%, p < 0.001). AEs were mild (83.8%), moderate (15.9%), and severe (0.3%), and most resolved within 72 h. The incidence of experiencing one, two, ≥ three types of AEs were 2.8%, 1.3%, and 0.6%, respectively. The most common AEs were headache (1.23%), drowsiness (1.15%), fever (1.12%), and dizziness (1.06%). A chronic illness, or clinical manifestation of lymphatic filariasis, or being female or pre-existing clinical symptoms were independent significant predictors of AEs. IA combination preventive chemotherapy is safe and tolerable, and associated AEs are mild-to-moderate and transient, with few severe AEs. Safety monitoring during MDA campaigns in individuals with underlying clinical conditions is recommended for timely detection and management of AEs.

Six publication

Title:

Efficacy of ivermectin and albendazole combination in suppressing transmission of lymphatic filariasis following mass administration in Tanzania: a prospective cohort study

Available at: https://pubmed.ncbi.nlm.nih.gov/38867265/ OR through DOI: 10.1186/s40249-024-01214-3

Preventive chemotherapy with ivermectin and albendazole (IA) in mass drug administration (MDA) programs for all at-risk populations is the core public health intervention to eliminate lymphatic filariasis (LF). Achieving this goal depends on drug effectiveness in reducing parasite reservoirs in the community to halt transmission. We assessed the efficacy of ivermectin and albendazole in clearing microfilariae and circulating filarial antigens (CFA) following MDA.

This community-based prospective study was conducted in Mkinga district, Tanga region, Tanzania, from November 2018 to June 2019. A total of 4115 MDA-eligible individuals were screened for CFA using Filarial test strips. CFA positives were re-examined for microfilariae by microscopy. CFA and microfilariae positive individuals were enrolled and received IA through MDA campaign. The status of microfilariae and CFA was monitored before MDA, and on day 7 and six-month following MDA. The primary efficacy outcomes were the clearance rates of microfilariae on day 7 and six-months, and CFA at 6 months of post-MDA. The McNemar test assessed the proportions of microfilariae positive pre- and post-MDA, while Chi-square tests were utilized to examine factors associated with CFA status six months post-MDA.

Out of 4115 individuals screened, 239 (5.8%) tested positive for CFA, of whom 11 (4.6%) were also positive for microfilariae. Out of the ten microfilariae-positive individuals available for follow-up on day 7, nine tested negative, yielding a microfilariae clearance rate of 90% [95% confidence interval (CI): 59.6-98.2%]. Participants who tested negative for microfilariae on day 7 remained free of microfilariae six months after MDA. However, those who did not clear microfilariae on day-7 remained positive six-months post-MDA. The McNemar test revealed a significant improvement in microfilariae clearance on day 7 following MDA (P = 0.02). Out of 183 CFA-positive individuals who were available at 6-month follow-up, 160 (87.4%) remained CFA positive, while 23 became CFA negative. The CFA clearance rate at 6 months post-MDA was 12.6% (95% CI: 8.5-8.5%). There was no significant association of variability in ivermectin plasma exposure, measured by maximum concentration or area under the curve, and the clearance status of microfilariae or CFA post-MDA.

Preventive chemotherapy with IA effectively clears microfilariae within a week. However, it is less effective in clearing CFA at six months of post-MDA. The low clearance rate for filarial antigenemia underscores the need for alternative drug combinations and additional preventive measures to achieve LF elimination by 2030.

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